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Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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<b>TRANSMITTAL FORM</b> <i>(to be used for all correspondence after initial filing)</i>	Application Number	10/612,852	
	Filing Date	July 3, 2003	
	First Named Inventor	Joel S. Douglas	
	Art Unit	3736	
	Examiner Name	Unassigned	
Total Number of Pages in This Submission		Attorney Docket Number	7404-543

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawings <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) <input type="text"/>	<input type="checkbox"/> After Allowance communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Return Receipt Postcard Form SB/08A Copy of Cited Foreign References
Remarks <input type="text"/>		
<b>SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT</b>		
Firm or individual name	Charles P. Schmal, Reg. No. 45,082 Woodard, Emhardt, Moriarty, McNett & Henry LLP	
Signature		
Date	October 4, 2004	

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re/patent application of:

John S. Douglas

Serial No.10/612,852

Filed July 3, 2003

**METHODS AND APPARATUS  
FOR SAMPLING AND  
ANALYZING BODY FLUIDS**

)  
) Before the Examiner  
) Unassigned  
)  
) Group Art Unit  
) 3736  
)  
) October 4, 2004  
)  
)

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**INFORMATION DISCLOSURE STATEMENT**

Honorable Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to the provisions of 37 CFR 1.56, 1.97 and 1.98, Applicant requests consideration of the references listed on attached form PTO-1449 (PTO/SB08A&B) and/or the additional information identified below in paragraph 4. A legible copy of each reference listed on form PTO-1449 is enclosed, except:

[ ] a copy is not provided for each reference previously cited by or submitted to the Patent Office in prior parent application Serial No. \_\_\_\_\_ filed \_\_\_\_\_ and/or

[X] a copy of each U.S. patent and/or U.S. patent application publication is not provided because the present application has been filed or entered the national stage after June 30, 2003 and the Patent Office has waived the requirements of 37 CFR 1.98 (a)(2)(i) for submitting such documents in applications filed or nationalized after June 30, 2003.

1a.

[X] This Information Disclosure Statement is submitted:

within three months of the filing date (or of entry into the National Stage) of the above-entitled application (other than a continued prosecution application), or

before the mailing date of the first Office Action on the merits,

**and thus no certification and/or fee is required.**

Information Disclosure Statement  
Serial No. 10/612,852  
Group Art Unit 3736  
Attorney Docket No. 7404-543  
Page 1 of 3

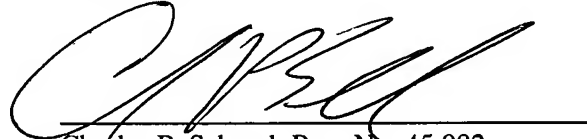
- 1b. ☐ This Information Disclosure Statement is submitted after the events of above paragraph 1a and prior to the mailing date of a final Office Action or Notice of Allowance, and thus:
- (1) ☐ the certification of paragraph 2 below is provided, or
- (2) ☐ a fee of **\$180.00** (set forth in 37 CFR §1.17(p)) is enclosed.
- 1c. ☐ This Information Disclosure Statement is submitted after the mailing date of a final Office Action or Notice of Allowance and prior to payment of the issue fee, and thus:
- (1) ☐ **the certification of paragraph 2 below is provided, and a fee of \$\_\_\_\_\_ (set forth in 37 CFR §1.17(p)) is enclosed; or**
- (2) ☐ a Request for Continued Examination (RCE) has been filed.
2. It is hereby certified
- a. ☐ that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement, or
- b. ☐ that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.
- c. ☐ A copy of a dated communication from a foreign patent office which clearly shows the statement is being submitted within three (3) months of the date on the communication is enclosed.
3. ☐ A copy of a Search Report or Written Opinion from a foreign patent office is enclosed.
4. ☐ Consideration of the following additional information (including any copending or abandoned U.S. application, prior uses and/or sales, etc.) is requested.

5. For each non-English language reference listed on the attached form PTO-1449, reference is made to:
- a. ☒ an English language translation submitted herewith,
  - b. ☐ a foreign patent office search report (in the English language) submitted herewith,
  - c. ☐ an English language translation of a foreign patent office search report submitted herewith,
  - d. ☐ the concise explanation contained in the specification of the present application at page<sup>s</sup> \_\_\_\_\_,
  - e. ☒ the concise explanation set forth in the attached English language abstract,
  - f. ☐ a copy of a related patent publication (in the English language) submitted herewith,
  - g. ☐ the concise explanation set forth below:

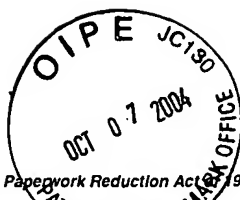
The filing of this Information Disclosure Statement shall not be construed as an admission that the information cited is, or is considered to be, material to patentability as defined in §1.56(b).

It is believed that no additional fees are required. Should any other fee be required, however, please charge such fee to Deposit Account No. 23-3030, but not to include any payment of issue fees.

Respectfully Submitted,



Charles P. Schmal, Reg. No. 45,082  
Woodard, Emhardt, Moriarty, McNett &  
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<b>Substitute for form 1183A/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/612,852
				Filing Date	7/3/2003
				First Named Inventor	DOUGLAS, J. ROE, RADWANSKI, DUCHO
				Group Art Unit	3736
				Examiner Name	Not Assigned
Sheet	1	of	7	Attorney Docket Number	7404-543

### U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Application of Cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
		Number-Kind Code (if known)			
		2,714,890	08-09-1955	Vang	
		3,086,288	04-23-1969	Balamuth et al.	
		3,208,452	09-28-1965	Stern	
		3,673,475	06-27-1972	Britton, Jr.	
		3,832,776	09-03-1974	Sawyer	
		4,077,406	03-07-1978	Sandhage et al.	
		4,154,228	05-15-1979	Feldstein et al.	
		4,203,446	05-20-1980	Hofert et al.	
		4,223,674	09-23-1980	Fluent et al.	
		4,230,118	10-28-1980	Holman et al.	
		4,356,826	11-02-1982	Kubota	
		4,449,529	05-22-1984	Burns et al.	
		4,462,405	07-31-1984	Erhlich	
		4,518,384	05-21-1985	Tarello et al.	
		4,535,773	08-20-1985	Yoon	
		4,553,541	11-19-1985	Burns et al.	
		4,750,489	06-14-1988	Berkman et al.	
		4,794,926	01-03-1989	Munsch et al.	
		4,823,806	04-25-1989	Bajada	
		4,995,402	02-26-1991	Smith et al.	
		5,047,044	09-10-1991	Smith et al.	
		5,097,810	03-24-1992	Fishman et al.	

Examiner Signature		Date Considered	
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

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				Filing Date	7/3/2003
				First Named Inventor	DOUGLAS, J. ROE, RADWANSKI, DUCHO
				Group Art Unit	3736
				Examiner Name	Not Assigned
Sheet	2	of	7	Attorney Docket Number	7404-543
<b>U.S. PATENT DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Application of Cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
		5,145,565	09-08-1992	Kater et al.	
		5,152,775	10-06-1992	Ruppert	
		5,188,118	02-23-1993	Terwilliger	
		5,189,751	03-02-1993	Giuliani et al.	
		5,222,504	01-29-1993	Solomon	
		5,320,808	06-14-1994	Holen et al.	
		5,415,169	05-16-1995	Siczek et al.	
		5,472,427	12-05-1995	Rammner	
		5,474,084	12-12-1995	Cunniff	
		5,514,152	05-07-1996	Smith	
		5,529,074	06-25-1996	Greenfield	
		5,575,403	11-19-1996	Charlton et al.	
		5,630,986	02-20-1997	Charlton et al.	
		5,632,410	05-27-1997	Moulton et al.	
		5,714,390	02-03-1998	Hallowitz et al.	
		5,720,924	02-24-1998	Eikmeier et al.	
		5,738,244	04-14-1998	Charlton et al.	
		5,758,643	06-02-1998	Wong et al.	
		5,776,157	07-07-1998	Thorne et al.	
		5,788,651	08-04-1998	Weilandt	
		5,800,781	09-01-1998	Gavin et al.	
		5,801,057	09-01-1998	Smart et al.	

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				First Named Inventor	DOUGLAS, J. ROE, RADWANSKI, DUCHO
				Group Art Unit	3736
				Examiner Name	Not Assigned
Sheet	3	of	7	Attorney Docket Number	7404-543

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		Number-Kind Code (if known)			
		5,810,199	09-22-1998	Charlton et al.	
		5,823,973	10-20-1998	Racchini, et al.	
		5,830,219	11-03-1998	Bird et al.	
		5,846,490	12-08-1998	Yokota et al.	
		5,854,074	12-29-1998	Charlton et al.	
		5,855,801	01-05-1999	Lin et al.	
		5,863,800	01-26-1999	Eikmeier et al.	
		5,871,494	02-16-1999	Simons et al.	
		5,880,829	03-09-1999	Kauhaniemi et al.	
		5,885,211	03-23-1999	Eppstein et al.	
		5,916,229	06-29-1999	Evans	
		5,935,075	08-10-1999	Casscells et al.	
		5,938,679	08-17-1999	Freeman et al.	
		5,951,582	09-14-1999	Thorne et al.	
		5,968,063	10-19-1999	Chu et al.	
		5,971,941	10-26-1999	Simons et al.	
		5,997,561	12-07-1999	Bocker et al.	
		6,027,459	02-22-2000	Shain et al.	
		6,036,924	03-14-2000	Simons et al.	
		6,048,352	04-11-2000	Douglas et al.	
		6,071,294	06-06-2000	Simons et al.	
		6,093,156	07-25-2000	Cunningham et al.	

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				Group Art Unit	3736
				Examiner Name	Not Assigned
Sheet	4	of	7	Attorney Docket Number	7404-543
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		6,117,630	09-12-2000	Reber et al.	
		6,120,462	09-19-2000	Hibner et al.	
		6,132,449	10-17-2000	Lum et al.	
		6,136,013	10-24-2000	Marshall et al.	
		6,139,562	10-31-2000	Mauze et al.	
		6,143,164	11-07-2000	Heller et al.	
		6,152,942	11-28-2000	Brenneman et al.	
		6,155,992	12-05-2000	Henning et al.	
		6,156,051	12-05-2000	Schrage	
		6,159,424	12-12-2000	Kauhaniemi et al.	
		6,171,325	01-09-2001	Mauze et al.	
		6,176,865 B1	01-23-2001	Mauze et al.	
		6,183,489 B1	02-06-2001	Douglas et al.	
		6,193,673 B1	02-27-2001	Viola et al.	
		6,203,504	03-20-2001	Latterell et al.	
		6,210,420 B1	04-03-2001	Mauze et al.	
		6,210,421 B1	04-03-2001	Bocker et al.	
		6,228,100 B1	05-08-2001	Schrage	
		6,231,531 B1	05-15-2001	Lum et al.	
		6,261,241 B1	07-17-2001	Burbank et al.	
		6,261,245 B1	07-17-2001	Kawai et al.	
		6,283,926	09-04-2001	Cunningham et al.	

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				First Named Inventor	DOUGLAS, J. ROE, RADWANSKI, DUCHO
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Sheet	5	of	7	Attorney Docket Number	7404-543
<b>U.S. PATENT DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Application of Cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
		6,285,454	09-04-2001	Douglas et al.	
		6,306,104 B1	10-23-2001	Cunningham et al.	
		6,306,152	10-23-2001	Verdonk et al.	
		6,315,738 B1	11-13-2001	Nishikawa et al.	
		6,319,210 B1	11-20-2001	Douglas et al.	
		6,332,871 B1	12-25-2001	Douglas et al.	
		6,364,889	04-02-2002	Kheiri et al.	
		6,364,890 B1	04-02-2002	Lum et al.	
		6,375,627	04-23-2002	Mauze et al.	
		6,379,317 B1	04-30-2002	Kintzig et al.	
		6,379,969 B1	04-30-2002	Mauze et al.	
		6,391,005 B1	05-21-2002	Lum et al.	
		6,402,701 B1	06-11-2002	Kaplan et al.	
		6,402,704 B1	06-11-2002	McMorrow	
		6,409,740	06-25-2002	Kuhr et al.	
		6,461,496	10-08-2002	Feldman et al.	
		6,472,220 B1	10-29-2002	Simons et al.	
		6,485,439 B1	11-26-2002	Roe et al.	
		6,488,891	12-03-2002	Mason et al.	
		6,491,709 B2	12-10-2002	Sharma et al.	
		6,497,845	12-24-2002	Sacherer	
		6,503,210	01-07-2003	Hirao et al.	

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				Application Number	10/612,852
				Filing Date	7/3/2003
				First Named Inventor	DOUGLAS, J. ROE, RADWANSKI, DUCHO
				Group Art Unit	3736
				Examiner Name	Not Assigned
Sheet	6	of	7	Attorney Docket Number	7404-543
<b>U.S. PATENT DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Application of Cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
		6,506,575	01-14-2003	Knappe et al.	
		US 2001/0031931 A1	10-18-2001	Cunningham et al.	
		US 2002/0002344 A1	01-03-2002	Douglas et al.	
		US 2002/0004196 A1	01-10-2002	Whitson	
		US 2002/0052618 A1	05-02-2002	Haar et al.	
		US 2002/0082543 A1	06-27-2002	Park et al.	
		US 2002/0103499 A1	08-01-2002	Perez et al.	

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1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

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Sheet	7	of	7	Attorney Docket Number	7404-543		
<b>FOREIGN PATENT DOCUMENTS</b>							
Examiner Initials*	Cite <sup>1</sup> No.	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Application of Cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>2</sup>	Number-Kind Code <sup>3</sup> (if known)				
		JP 04194660	A1	11-27-1990	Omron Corp		<input checked="" type="checkbox"/>
		JP 2000116768	A2	04-25-2000	Terumo Corp		<input checked="" type="checkbox"/>
		WO 01/00090	A1	01-04-2001	Vos		<input type="checkbox"/>
		WO 01/34029	A1	05-17-2001	ARKRAY, INC.		<input type="checkbox"/>
		WO 01/66010	A1	09-13-2001	Fritz et al.		<input type="checkbox"/>
		WO 02/056769	A1	07-25-2002	MATSUSHITA EL		<input type="checkbox"/>
		WO 97/42888		11-20-1997	Douglas et al.		<input type="checkbox"/>

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